IN THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Withdrawn) A therapeutic agent for treating HIV infection, comprising an immunostimulatory recombinant Tat protein.

2. (Withdrawn) The therapeutic agent according to claim 1, wherein the Tat protein consists of amino acids 1-72 of wild-type Tat or peptide derivatives thereof.

3. (Withdrawn) The therapeutic agent according to claim 1, wherein the Tat protein consists of amino acids 1-86 of wild-type Tat or peptide derivatives thereof.

4. (Withdrawn) The therapeutic agent according to claim 1, wherein the Tat protein consists of mTat l-86, wherein amino acid 22 is Gly-22 or other mutations in the protein.

5. (Withdrawn) The therapeutic agent according to claim 1, further comprising one or more adjuvants.

6. (Withdrawn) The therapeutic agent according to claim 5, wherein the adjuvant is selected from the group consisting of alum, HPC and lipid A.

7. (Withdrawn) The therapeutic agent according to claim 1, in particulate form.

8. (Withdrawn) The therapeutic agent according to claim 1, wherein the Tat protein is obtained by a process comprising the steps of:

biosynthesizing Tat in a bacterial cell culture;

producing a crude isolate of Tat;

removing bacterial RNA from Tat; and

isolating Tat from endotoxin.

9. (Withdrawn) The therapeutic agent according to claim 8, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

10. (Withdrawn) The therapeutic agent according to claim 9, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

11. (Withdrawn) The therapeutic agent according to claim 8, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

12. (Withdrawn) The therapeutic agent according to claim 11, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

13. (Withdrawn) A method to induce humoral and cellular responses using an immunostimulatory recombinant Tat protein that is autonomously internalized by cells.

14. (Withdrawn) The method according to claim 13, wherein the Tat protein consists of amino acids 1-72 of wild-type Tat or peptide derivatives thereof.

15. (Withdrawn) The method according to claim 13, wherein the Tat protein consists of amino acids 1-86 of wild-type Tat or peptide derivatives thereof.

16. (Withdrawn) The method according to claim 13, wherein the Tat protein consists of mTat 1-86, wherein amino acid 22 is Gly-22 or other mutations in the proteins.

17. (Withdrawn) The method according to claim 13, wherein the Tat protein is obtained by a process comprising the steps of:

biosynthesizing Tat in a bacterial cell culture;

producing a crude isolate of Tat;

removing bacterial RNA from Tat; and

isolating Tat from endotoxin.

18. (Withdrawn) The method according to claim 17, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

19. (Withdrawn) The method according to claim 17, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

20. (Withdrawn) The method according to claim 17, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

21. (Withdrawn) The method according to claim 17, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

22. (Withdrawn) A process for producing a Tat protein, said process comprising the steps of:

biosynthesizing Tat in a bacterial cell culture;

producing a crude isolate of Tat;

removing bacterial RNA from Tat; and

isolating Tat from endotoxin.

23. (Withdrawn) The process according to claim 22, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA

coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

24. (Withdrawn) The process according to claim 22, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

25. (Withdrawn) The process according to claim 22, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

26. (Withdrawn) The process according to claim 22, wherein the step for isolating Tat from cytotoxin comprises exposing Tat to a polymixin column to remove cytotoxin.

27. (Withdrawn) A process of making Tat that is non-denatured and free of Bacterial RNA and endotoxin, the process comprising the steps of:

subcloning Tat into a bacterial vector as a N-terminally biotinylated fusion protein;

transforming a bacterial host with the cloned bacterial vector to express the fusion protein in the bacterial host;

isolating the fusion protein on an avidin column;

cleaving Tat from the fusion protein;

digesting RNA from Tat in the presence of RNAse; and

removing endotoxin from Tat;

the foregoing steps producing said non-denatured, bacterial RNA- and endotoxin- free Tat.

28. (Withdrawn) Non-denatured, bacterial RNA-free and endotoxin-free Tat.

29. (Withdrawn) The use of Tat for inducing an immune response.

30. (Withdrawn) A method of treating HIV infection comprising administering to a subject in need thereof, an immune-response inducing effective amount of the therapeutic agent of claim 1.

31. (Withdrawn) The method of claim 30 wherein the therapeutic agent further comprises an adjuvant.

32. (Withdrawn) The method according to claim 31, wherein the adjuvant is selected from the group consisting of alum, HPC and lipid A.

33. (Currently Amended) [[A]] An immunogenic composition comprising Human Immunodeficiency Virus (HIV) Tat adsorbed to the surface of anionic nanoparticles, by electrostatic interactions,

wherein said composition is capable of inducing strong humoral and cell-mediated anti-Tat responses ~~Tat-absorbed nanoparticle, for treating and preventing HIV infection, wherein the adsorption efficiency of Tat to the nanoparticles is approximately 100%.~~

34. (Currently Amended) The nanoparticle according to claim 33, wherein the Tat consists of amino acids 1-72 of wild-type Tat ~~or peptide derivatives thereof~~.

35. (Original) The nanoparticle according to claim 33, wherein the Tat consists of amino acids 1-86 of wild-type Tat ~~or peptide derivatives thereof~~.

36. (Currently Amened) The nanoparticle according to claim 33, wherein the Tat consists of mTat 1-86, wherein amino acid 22 is mutated to glycine ~~Gly-22 or other mutations in the protein~~.

37. (Currently Amended) [[The]] An immunogenic composition comprising Human Immunodeficiency Virus (HIV) Tat-absorbed nanoparticles obtained by a process comprising the steps of:

(a) producing a Tat protein according to the process comprising:

(1) biosynthesizing Tat in a bacterial cell culture;

(2) producing a crude isolate of Tat;

(3) removing bacterial RNA from the crude isolate of Tat; and

(4) isolating Tat protein from endotoxin in the crude isolate of step (3);

(b) preparing purified anionic nanoparticles from microemulsion precursors; and

(c) mixing the purified nanoparticles with the Tat protein from step (4),

wherein said Tat is adsorbed to the surface of said nanoparticles through electrostatic interactions and said Tat-adsorbed nanoparticles are capable of inducing strong humoral and cell-mediated anti-Tat immune responses.

38. (Currently Amened) The Tat-adsorbed nanoparticles according to claim 37, wherein the step for biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

39. (Currently Amended) The Tat-adsorbed nanoparticles according to claim 38, wherein the step for biosynthesizing Tat in a bacterial cell culture further comprises eluting the cleaved Tat from the avidin resin.

40. (Currently Amended) The Tat-adsorbed nanoparticles according to claim 37, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

41. (Currently Amended) The Tat-adsorbed nanoparticles according to claim 37, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

42. (Currently Amended) The Tat-adsorbed nanoparticles according to claim 37, further comprising incubating the mixture of purified nanoparticles and Tat with phosphate-buffered saline, fetal bovine serum in normal saline, or lactose.

43. (Withdrawn-Currently Amended) A process for producing ~~a Tat-adsorbed nanoparticle~~ an immunogenic composition comprising Human Immunodeficiency Virus (HIV) Tat adsorbed to the surface of anionic nanoparticles, by electrostatic interactions,

wherein said composition is capable of inducing strong humoral and cell-mediated anti-Tat responses

comprising the steps of:

(a) producing a Tat protein

comprising the steps of:

(1) biosynthesizing Tat protein in a bacterial cell culture;

(2) producing a crude isolate of Tat;

(3) removing bacterial RNA from the crude isolate of the Tat;

(4) isolating Tat protein from endotoxin in the crude isolate of step (3),

and

(b) mixing nanoparticles with the Tat protein of step (4)~~, wherein the adsorption efficiency of Tat to the nanoparticles is approximately 100%.~~

44. (Withdrawn) The process according to claim 43, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

45. (Withdrawn) The process according to claim 43, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

46. (Withdrawn) The process according to claim 43, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

47. (Withdrawn) The process according to claim 43, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

48. (Withdrawn) The process according to claim 43, further comprising incubating the mixture of purified nanoparticles and Tat with phosphate-buffered saline, fetal bovine serum in normal saline, or lactose.

49. (Withdrawn-Currently Amended) A method to induce humoral and cellular responses comprising administering to a subject in need thereof, an effective amount of ~~a Tat-adsorbed nanoparticle~~ an immunogenic composition comprising Human Immunodeficiency Virus (HIV) Tat adsorbed to the surface of anionic nanoparticles, by electrostatic interactions.

50. (Withdrawn) The method of claim 49, wherein the cellular response is a Th1-type response.

51. (Withdrawn-Currently Amended) A method of treating HIV infection comprising administering to a subject in need thereof, an immune-response inducing effective amount ~~of a Tat-adsorbed nanoparticle~~

an immunogenic composition comprising Human Immunodeficiency Virus (HIV) Tat adsorbed to the surface of an anionic nanoparticles, by electrostatic interactions.

52. (Currently Amended) A Tat-adsorbed nanoparticle delivery system for the delivery of protein antigens comprising the ~~Tat-adsorbed~~ nanoparticles according to claim 33.

53. (Currently Amended) The process for producing ~~a Tat-adsorbed nanoparticle~~ the nanoparticles of claim 43, further comprising the step of preparing purified anionic nanoparticles from microemulsion precursor.